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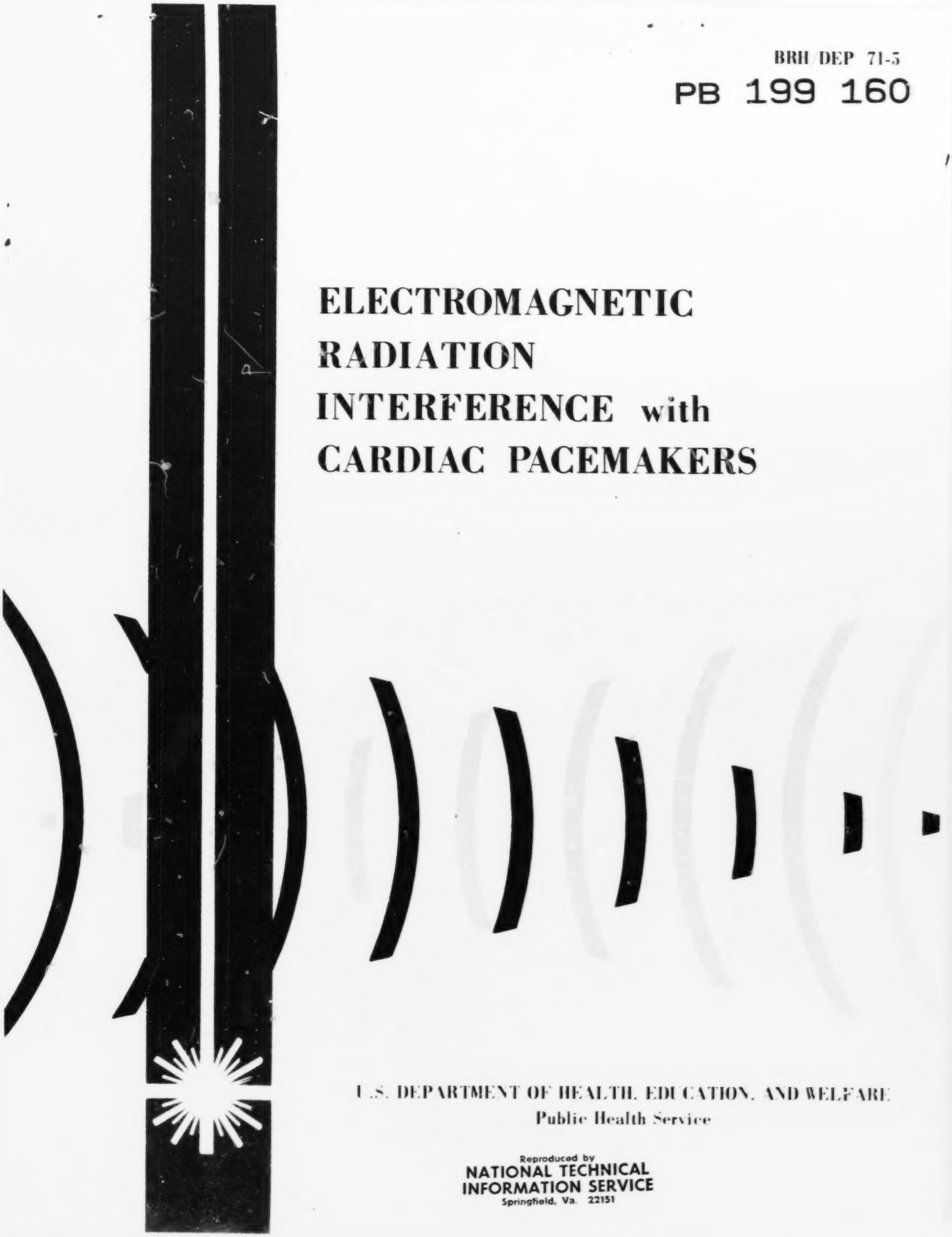
# ELECTROMAGNETIC RADIATION INTERFERENCE with CARDIAC PACEMAKERS



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# ELECTROMAGNETIC RADIATION INTERFERENCE with CARDIAC PACEMAKERS

Paul S. Ruggera and Robert L. Elder, Sc.D
Division of Electronic Products

April 1971

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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# FOREWORD

The Bureau of Radiological Health continues to carry out a national program designed to reduce the exposure of man to hazardous ionizing and nonionizing radiation.

Within the Bureau, the Division of Electronic Products (1) develops and administers performance standards for radiation emissions from electronic products, (2) studies and evaluates emissions of and conditions of exposure to electronic product radiation and intense magnetic fields, (3) conducts or supports research, training, development, and inspections to control and minimize such hazards, and (4) tests and evaluates the effectiveness of procedures and techniques for minimizing such exposures.

The Bureau publishes its findings in appropriate scientific journals and technical report and technical note series for the Bureau's divisions, offices, and laboratories.

The technical reports and notes of the Division of Electronic Products allow comprehensive and rapid publishing of the results of intramural and contractor projects. The reports and notes are distributed to State and local radiological health program personnel, Bureau technical staff, Bureau advisory committee members, university radiation safety officers, libraries and information services, industry, hospitals, laboratories, schools, the press, and other interested individuals. They are also included in the collections of the Library of Congress and the National Technical Information Service.

I encourage the readers of these reports to inform the Bureau of any omissions or errors. Your additional comments or requests for further information are also solicited.

John C. Villforth
Director
Bureau of Radiological Health

## PREFACE

Electromagnetic radiation interference with cardiac pacemkaers has been studied and reported in some detail since pacemakers were first developed. Most of the literature concerns those products and frequency ranges with which a person would most likely come in contact during normal daily existence. Implanted pacemaker disfunction has been observed near electrocautery and diathermy apparatus, radar and communications systems, electric shavers, spark coils, and gasoline ignition systems. With the recent and anticipated expansion of the use of microwave ovens in residences, hospitals, and commercial establishments, the possibility of microwave oven interference with pacemaker function must also be considered.

This report describes pacemaker function and explains the mechanism of electromagnetic interference. It also outlines the status of Division of Electronic Products activities relating to the problem of potential pacemaker malfunction as a result of interference from microwave oven radiation.

Robert L. Elder, Sc.D.
Director
Division of Electronic Products

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## ABSTRACT

The Division of Electronic Products has initiated a study to determine the relative danger presented to cardiac pacemaker patients by the microwave oven in comparison with other known sources of electromagnetic interference. This report explains how pacemakers and microwave ovens function, describes the mechanism of electromagnetic interference, and outlines the status of Division of Electronic Products activities in this area.

# ELECTROMAGNETIC RADIATION INTERFERENCE

## - CARDIAC PACEMAKERS -

## 1. INTRODUCTION

The rhythmic pumping action of the human heart is controlled by a series of electrical impulses which cause the muscles to alternately contract and relax. A healthy heart functions properly and does its job as long as some biological mechanism does not deplete its parts of the energy required to generate and distribute these impulses. When a malfunction in the heart's electrical system does occur, a cardiac pacemaker can sometimes be used to provide a supplemental source of stimulation. Like the heart, the pacemaker functions as designed and does its job only as long as its parts, whose function depends upon a flow of electrons, are not deprived of the proper amount and sequence of these electrons. As man's technology continues to increase, so does the number of electronic devices in use and so does the number of circuit-produced electrical fields which can interact with other electrical fields. Some of these, such as radio and television transmitters and receivers, are examples of circuits which interact to produce a favorable result. Circuits which react with the pacemaker, however, can produce unfavorable and unwanted results.

Studies concerning the susceptibility of implanted cardiac pacemakers to external electromagnetic interference have been underway for the past decade. Unfortunately, good quantitative data regarding the levels of induced energy necessary for pacemaker malfunction have not been reported. Nevertheless, it has been established that apparatus used in the hospital environment can disrupt pacemaker function. Disfunction has been observed near diathermy units (1,2,3) and during operations in which electrocautery was used (2,4). Outside the hospital, pacemaker disfunction has been reported in the vicinity of the following: radio stations (1,5); motorcycles and gasoline ignition systems (3,4); radar sites (6); an electric shaver and a television receiver (7); as well as an electric mixer (8). This brief list is not intended to be all inclusive, but serves to point out the wide variety of potential interference sources presented daily to the pacemaker wearer. Physicians have been alerted to the potential interference from electronic products through the available literature, and they, in turn, have been able to advise their pacemaker patients on possible problems.

Recently, the use of the microwave oven, another electronic product relatively new to the consumer market and capable of affecting pacemaker function, has been increasing. A letter to the editor in the May 18, 1970, issue of the Journal of the American Medical Association (9) reported two pacemaker patients who exhibited Stokes-Adams syndrome (symptomatic of the type of heart malfunction the pacemaker is designed to counteract) in the vicinity of an operating microwave oven. Since that time many inquiries, both public and private, have been received about the effect of microwave ovens on cardiac pacemakers.

The Department of Health, Education, and Welfare recently promulgated a standard for microwave ovens which specifies maximum levels of leakage. When it became apparent that the levels specified in the standard would not necessarily protect the pacemaker wearer, the Division of Electronic Products, Bureau of Radiological Health, began an investigation to determine the relative danger presented by the microwave oven in comparison with other potential known sources of interference. This report explains how pacemakers and microwave ovens function, explores the mechanism of interference, and outlines the activities of the Division of Electronic Products which relate to this situation of public concern. A bibliography of articles on the subject of pacemaker interference has also been prepared and is included for reference.

# 2. HEART AND PACEMAKER FUNCTION

## 2.1 THE NORMAL HEART

To maintain life, an organism must obtain energy from its environment, efficiently utilize and convert this into life processes, and eliminate the accumulated waste products. The internal transport system in the human by which this vital process is carried out is the circulatory system. Volumes have been written on the many aspects of this energy transfer, and it is unnecessary to belabor the point. The fact remains, however, that if the blood does not circulate, life does not exist. At the center of this vital system is the heart. It beats an average of 72 times a minute in the normal human. It has the capability to adjust to the needs of the body by increasing or decreasing its rate as demanded by the activity of the subject. It begins its function a few months after conception and continues until death.

The heart, as with any other life form, is not perfect. It is susceptible to disease, and its functioning parts can deteriorate. If this deterioration is not complete, however, life will be sustained. The price paid for this condition is decreased mobility which results from inefficient and reduced cardiac output. In times past there was little that could be done to alleviate this situation. With the advent of new surgical techniques, along with vast technological advances, the physical means is now available to correct some of the malfunctions of the heart and thus return it to peak physiological efficiency.

The aspect of normal heart function with which this report is concerned is the electrical conduction system in the heart itself. The human heart is a four-chamber pump. The two smaller, upper chambers, the atria, receive blood from the lungs and the body; the lower larger chambers, the ventricles, deliver blood to the lungs and body. For efficient use of this type pump, the body has developed a sequence of events which take place in rhythmic order. These events are controlled by electrical impulses distributed through various nerve fibers in the heart muscle. The sino-atrial node maintains the rate at which these events take place. It generates a signal which causes the atria to contract, thus forcing blood into the ventricles. As the ventricles are filling, the nerve impulse is conducted through a nerve bundle to the lower extremity of the ventricles where it stimulates the muscle fibers and causes the squeezing and subsequent emptying of the ventricles. The heart then relaxes, the atria refill, and the sequence repeats.

## 2.2 THE NEED FOR A PACEMAKER

When the physiological conduction paths in the heart are broken, the sequence of contractions will be random and low cardiac output will result. One of these paths, the sino-atrial node, stimulates the atria and is called the physiological pacemaker. The current consumer market does not offer a device to substitute for the sino-atrial node. The other conduction path leads from the atria to the ventricles. If this path is broken, the atria will continue to beat at a normal rate of about 72 beats per minute, but the ventricles will maintain a rate of only 30 to 40 beats per minute (the rate inherent to ventricular muscle). This condition, known as atrioventricular (AV) heart block, can be corrected by the use of a cardiac pacemaker -- an electronic device capable of stimulating the ventricles to a higher and more natural rate.

When a person experiences an acute deficiency of cerebral blood flow, he exhibits symptoms classified by the medical profession as Stokes-Adams syndrome. "Stokes-Adams syndrome may be manifested clinically by a wide spectrum of symptoms and signs. These include transient faintness; giddiness; blackouts and fainting episodes; 'dizziness' and foggy mental state, especially in the standing position; sudden syncope, convulsions and cerebral seizures; cardiac arrest and shock; and acute cerebrovascular insufficiency with stroke. In all these clinical states, the AV (atrioventricular) block may be chronic or intermittent."(10)

The cardiac pacemaker is used in cases of chronic (long-term and recurrent) AV heart block. In most pacemaker patients the atria are functioning near normal; the signal to the ventricles, however, is intermittent or absent. As mentioned earlier, when this occurs the ventricles take up their own natural rhythm of 30 to 40 beats per minute, and, while this rate is not desirable, it is not necessarily fatal and can be corrected by the use of the pacemaker.

## 2.3 PACEMAKER DESIGN

In most electronic products, the desired function may be accomplished by different designs and circuits. This holds true in the case of pulsing the ventricles at a near-normal rate. As little as five years ago, the most widely used method was to pulse the ventricles at a continuous, preset rate. Since no attempt was made to correlate the pacemaker pulses with the natural pulses, this was known as the asynchronous pacing method. The asynchronous method did not allow the heart rate to vary with activity of the patient but did allow far more activity than was available before pacing. This type of pacemaker is still used in some patients with complete AV block. Current versions of this pacemaker incorporate an oscillator which does not appear to be greatly influenced by the presence of external electromagnetic radiation.

As technology has developed, it has become possible to design the more desirable and now widely-used synchronous type of pacemaker. Circuits were built that allowed sensing of the depolarizations of the heart muscle itself. The synchronous pacemaker uses these signals as a reference and acts only if the normal heart depolarizations are not available. The heart rate can change with the individual's activity since this pacemaker does not interfere with any physiologically-originated impulse. This system can be used in patients with partial AV block without fear of introducing an extra beat in a critical portion of the cardiac cycle which could induce ventricular fibrillation (a condition during which coordinated contraction cannot occur). Because of the low-level energy-sensing portions of these circuits, however, these devices are susceptible to levels of electromagnetic interference which do not affect the asynchronous models.

Individual manufacturers have used several names to describe the various synchronous pacemakers. The end result, that of synchronizing the ventricles with the blood flow from the atria, is the same. The difference is in the way the synchronizing signal is detected and the manner in which it is or is not applied to the ventricles. Atrial-synchronous pacemakers sense the depolarization of the atria, delay the signal to simulate natural conduction time, and then deliver it to the ventricles. Ventricular-synchronous pacemakers sense the depolarization of the ventricles. An example of this latter type is the "ventricular-inhibited" pacemaker which senses the depolarization of the ventricles if it occurs naturally and then, by inhibiting its output, does nothing. Differences in circuitry in the ventricular-synchronous models are not of particular concern in that the signal level necessary for sensing in all of the various modes is relatively the same. The atrial-synchronous models require somewhat more sensitivity since the depolarization of the atria is less than that of the ventricles.

The sensing circuit of the ventricular-synchronous pacemaker is programmed to respond to signals lower than those generated by the heart, the range of which is 5 to 15 millivolts (11). Should energy induced externally, either on the electrode itself or in part of the pacemaker circuitry, allow the applied voltages to components to increase above design specifications, normal pacemaker function would be disrupted. The degree of the disfunction is dependent on the rate at which the excess energy can be dissipated. For instance, if excess energy is stored in the circuitry that prevents the parts from functioning, the pacemaker probably would stop -- at least until the source is removed. On the other hand, if the energy is not sufficient to inhibit a part's function, conceivably it could alter the part's output, and the pacemaker subsequently would respond and change its rate. In the first instance, the pacemaker-dependent patient would be returned to AV block; in the second, if the pacemaker rate increased, his heart could be stimulated to fibrillation.

## 3. ELECTROMAGNETIC INTERFERENCE FROM MICROWAVE OVENS

In accordance with the requirement of the Radiation Control for Health and Safety Act of 1968 that the public health and safety be protected from the dangers of electronic product radiation, a radiation standard for microwave ovens has been promulgated by the Department of Health, Education, and Welfare. The standard specifies that after October 6, 1971, newly manufactured ovens must not emit radiation at a power density exceeding 1 $mW/cm^2$ at any point 5 cm from the oven surface. To allow for wear after sale, the standard provides that the power density may increase to 5 $mW/cm^2$. It is estimated that 175,000 microwave ovens will be in use under the industry's present self-imposed standard of 10 $mW/cm^2$ before the new Federal standard becomes effective.

The implication that an electronic product, manufactured under standards thought to be safe for all persons exposed to it, would affect the functioning of an implanted pacemaker necessitated further investigation of that product's potential for interference. Two factors should be taken into consideration in such an investigation. The first is the frequency of the radiated energy which dictates antenna length for efficient capture of energy; the second is the shielding capability of the human body at the given frequency.

The frequency at which most of the commercially available ovens operate is 2450 MHz.[1] At this frequency the antenna length necessary for efficient capture of available external energy is small, perhaps a few centimeters. The leads of a transistor in the pacing circuit, therefore, may be a good antenna. The unshielded electrode which carries the signals to and from the heart offers another potentially efficient receiving antenna.

The amount of energy presented to an implanted pacemaker depends on the shielding capability of the body. This will vary considerably from person to person because of differences in placement procedures used in the implantation as well as in the physical size of the patient.

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[1] One manufacturer has a model available for home use which operates at 915 MHz.

In an attempt to determine the transparency of the human body to this frequency and thereby establish the relative amount of energy available, it should be noted that: "The relative absorptive cross-section is defined as the ratio of the power absorbed from the incident field relative to the power that would be incident on the object's geometric cross-section prior to its insertion into the field. The relative absorptive cross-section of mankind may vary from 50 to 100 percent for frequencies between 400 and 1000 MHz; it may vary from 20 to 100 percent for frequencies between 1000 and 3000 MHz; it is about 50 percent for frequencies between 3000 and 10,000 MHz." (12)

Assume that,as a general situation, 50 percent of the incident power from a microwave oven is absorbed by the body and is not available to the pacemaker or its electrode. The microwave oven performance standard calls for a maximum average leakage of 5 $mW/cm^2$ for the life of the product, measured at 5 cm from the surface. At this rate of leakage, assuming a planar wave, a power density of 5.4 $\mu W/cm^2$ would exist 5 feet from the oven. The electric field intensity in air at the same distance is approximately 44 mV/cm. Assuming that the body absorbs 50 percent of this, 31 mV could be available to every centimeter of exposed circuitry. Comparing this to the 5- to 15-mV sensitivity of the pacemaker, the probability of interference cannot be dismissed. An additional factor must be considered at this point. It is known that the output waveforms from microwave ovens are modulated. Therefore, the peaks would possess much more energy than the average cited above, and the probability of pacemaker malfunction would be greater.

## 4. SUMMARY OF DIVISION OF ELECTRONIC PRODUCTS ACTIVITIES

The problem of electromagnetic interference from microwave ovens with cardiac pacemakers was brought to the attention of the Division of Electronic Products (DEP), Bureau of Radiological Health, through the previously-mentioned letter to the editor in JAMA (9). After an interview with one of the authors of the letter regarding the procedures followed during patient observation, it was decided that further investigation of electromagnetic interference with pacemakers was warranted.

DEP was informed by a reliable electromagnetic interference testing company that currently-manufactured pacemakers could be made to change rate, especially when the interference was around 1 Hz or near the paced frequency. The company also noted that when the circuit was packaged in metal rather than in the clear epoxy-type package commonly used, its resistance to interference seemed greater. The information was based on tests of 14 pacemakers of several types available, representing more than one manufacturer. The tests were conducted both in free space and in a saline solution for the frequency spectrum of 20 Hz to 1 GHz. The maximum field strength was 10 V/m, and only broad face orientation to the source was tested. Apparently, in no case did the company observe pacemaker shutdown as was reported in JAMA.

To obtain more information, DEP wrote to eight domestic manufacturers on June 16, 1970, requesting information in the following areas: pacemaker types manufactured; quantitative data or reports; any specific data at 2450 MHz or 915 MHz (the two frequencies commonly used in microwave ovens); the most susceptible type of pacemaker; the energy levels; pulse repetition rates necessary to activate the sensing models; the possibility of shielding the pacemaker; and the estimated total number now in use.

A recognized expert in pacemaker design was contacted on June 17, 1970, for assistance in interpreting information and to obtain another opinion on the interference problem. During a discussion the following day, he provided information about work done at a company which had performed extensive pacemaker testing using microwave ovens. He reported that the company had determined that the microwave frequency acted as an efficient carrier into the body and could cause pacemaker failure. In addition, some ovens have stirrers which cycle at 1 Hz, producing a wave similar in time to the heartbeat. The sensing pacemaker apparently interprets this as the heart depolarization and fails to pulse the heart.

On June 22, 1970, a meeting was held with IITRI (IIT Research Institute) and BRH (Bureau of Radiological Health) personnel. The technical portion of the meeting concerned a discussion of IITRI's publication "Hazardous Electromagnetic Interaction with Medical Electronics"(13), with an emphasis on the work done by IITRI using an asynchronous pacemaker. Their conclusion is that any signal with fast rise time, therefore containing many high-frequency components, is capable of disrupting pacemaker function. IITRI presented some theoretical transmission calculations obtained from a model of a double-walled 16-inch sphere with a 1-inch wall thickness and filled with saline. Frequency periodic transmission peaks (0-2db attenuation) were observed at frequencies above 300 MHz. (This is another expression of the Anne work on frequency dependence of relative absorptive cross section referenced earlier.)

As of July 16, 1970, the response from manufacturers to the letter sent out a month earlier, although offering no quantitative data, did indicate that the possibility of interference existed. On that date, a letter prepared by DEP was sent to JAMA reemphasizing the possibility of microwave oven interference with certain types of cardiac pacemakers. It advised physicians to warn their patients of the possible hazard.

During the week of August 3, BRH conducted a survey in conjunction with the Veterans Administration as a preliminary effort to study the effects of microwave ovens and other medical apparatus on pacemaker function. The VA had obtained demand pacemakers from four domestic manufacturers. Hospitals chosen for the survey were located in New York, N.Y.; East Orange, N.J.; and Philadelphia, Pa. A degree of susceptibility was observed when one pacemaker was compared with another during exposure to the microwave oven fields. Some models exhibited a greater change in output rate than others. This difference in relation to the change caused by electrosurgical and diathermy units was less pronounced. All responded by pulsing at a rate several times that of the normal rate. When the model found most susceptible to microwave radiation was tested near ultrasonic cleaners and cavitrons, it also showed variation in rate.

On August 14, 1970, DEP held a briefing review for the purpose of informing the National Institutes of Health and the Food and Drug Administration of BRH activities concerning pacemakers.

As a result of this briefing, FDA called a meeting of several associations representing the medical community on August 25, 1970. The action decided upon at that time was as follows: (1) the problem did not represent a health hazard of such seriousness as to warrant a press release; (2) the pacemaker manufacturers should be contacted to determine what they are doing to minimize the interference problem; (3) the American Heart Association was to write a pamphlet for pacemaker wearers; and (4) hospital and physical therapy department personnel should be notified and cautioned about potential sources of interference.

On September 10, 1970, FDA called together representatives of several pacemaker manufacturers. The course of action suggested at the August 25, 1970, meeting was presented for their consideration. Some of the representatives stated that warnings on products known to interfere with pacemaker function were contained in their patient booklets. The manufacturers agreed to publish two letters under the auspices of their professional organization, the Association for the Advancement of Medical Instrumentation (AAMI). One was to be sent to hospital administrators and the other to physiatrists and physiotherapists. They also assured BRH and FDA that interference testing was underway and that future models would be less susceptible to electromagnetic interference.

In the meantime, DEP prepared and distributed a fact sheet on cardiac pacemaker interference to its ten regional radiological health representatives and to FDA for their use in answering questions on the subject.

The fact sheet and a prototype letter prepared by AAMI were used to compose a letter to hospital administrators. The content was agreed upon by FDA, BRH, AAMI and AHAM (Association of Home Appliance Manufacturers). On October 12, 1970, the letter was distributed to between 7,000 and 8,000 hospital administrators. Authorization for BRH dissemination to other public health agencies was also received.

On November 17, 1970, the contents of a letter similar to the previous one, but emphasizing the physical therapy aspect of interference, was composed. This was distributed in early January 1971 to all members of the American Congress of Rehabilative Medicine and the American Academy of Physical Medicine and Rehabilitation. The combined membership of both organizations is approximately 3,500 persons. The two letters are included as an appendix to this report.

## 5. CONCLUSIONS

Through meetings with representatives of the scientific, medical, and manufacturing community, it was decided that although leakage radiation from microwave ovens could cause some pacemakers to malfunction, the oven should not be singled out as the only or the most dangerous source of interference. Wide-scale distribution of warnings through professional channels has been effected through letters to those most capable of informing the pacemaker wearer of the overall interference problem. These warnings mention several potential sources of interference, one of which is the microwave oven.

The Bureau of Radiological Health has received assurance from pacemaker manufacturers that future pacemakers will be less susceptible to all forms of electromagnetic interference. It is the view of BRH that the combined program directed at informing the hospitals, physicians, and public health authorities, and thereby ultimately informing the patient, is the most responsible action that can be taken at this time. Concurrent with this distribution of information, BRH and professional societies are cooperating in the development of a testing program to determine the susceptibility of the various pacemaker designs to electromagnetic interference. Once these criteria are established, tests on production models will be carried out.

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# APPENDIX

Letters from

The Association for the Advancement of Medical Instrumentation

TO

Hospital Administrators

AND

Members of the American Congress of Rehabilitation Medicine
and Members of the American Academy of Physical Medicine
and Rehabilitation

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ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

9650 Rockville Pike, Bethesda, Maryland 20014
Telephone: (301) 530-2800

AAMI

TO: Members of the American Congress of Rehabilitation Medicine and Members of the American Academy of Physical Medicine and Rehabilitation

FROM: AAMI Pacemaker Standards Subcommittee

SUBJECT: Microwave Radiation and Pacemakers

Summary: Microwave radiation, in addition to other sources of electrical field interference, can modify the function of some pacemakers under certain conditions. Diathermy, therefore, should be used on pacemaker patients only with recognition of the hazardous interference potential. Also, persons who wear pacemakers and might operate or be in the very close proximity of operating microwave diathermy antennas should be aware of the potential hazard.

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External electrical interference has been studied and reported in some detail since pacemakers were first developed. Most of the literature concerns those products and frequency ranges that the person would most likely come in contact with in a normal daily existence. In rare cases, implanted pacemaker dysfunction has been observed near electrocautery and diathermy apparatus; microwave ovens, radar and communications systems; electric shavers, spark coils, and gasoline engine ignition systems. With the recent and anticipated expansion of the use of microwave appliances in hospitals, it is well to be cognizant of the potential interference problems.

The body, a conductive medium, provides good shielding from most interfering sources. However, external noncompetitive pacemakers and units designed for implantation, when tested externally, are much more susceptible to electrical interference, and therefore of greater concern.

There are two major classifications of pacemakers, the fixed (asynchronous) rate type and the noncompetitive type (i.e., demand, standby, ventricular, inhibited, ventricular triggered, atrial triggered). These pacemaker units may be implanted internally, within the body, or may be attached externally, outside the body.

The fixed rate pacemaker has a low frequency oscillator designed to deliver pulses at the desired cardiac stimulation rate. Such units are unaffected by any electrical interference situation which the patient may encounter, with the exception of electric cautery used within a few inches of the unit and R-F diathermy applied directly to the pacemaker site. In addition to the oscillator, the noncompetitive pacemaker contains electronic circuitry (designed to sense electrical cardiac activity), to modify the output of the pacemaker, should a natural contraction occur within the prescribed timing interval. This type of pacemaker is susceptible to microwave radiation of sufficient intensity. Diathermy should not be used on pacemaker patients without full recognition of the interference potential.

Any interference signal entering the electronic circuitry of the noncompetitive pacemaker, which mimics the electrical signal corresponding to a normal heartbeat, may be interpreted by the pacemaker as a normal heartbeat and cause changes in the pacemaker's output.

The patient's response to these effects on his pacemaker will depend on the mode of operation of the pacemaker, his individual cardiac condition and whether the pacemaker is implanted or external. Depending upon the type of pacemaker, it may speed-up - producing limited tachycardia, revert to a fixed rate, or inhibit its output. Patients with ventricular inhibited pacemakers may have a normal cardiac rate without pacing. These patients would likely feel nothing, as the heart has already inhibited the pacemaker. If the patient's nonpaced rate is quite low and the pacemaker is totally inhibited by the interference, the patient might experience dizziness and possible loss of consciousness (Stokes-Adams Syndrome). Such inhibition can be hazardous to the patient who is totally pacemaker dependent. It is important to recognize that the pacemaker is not damaged by electrical interference and will resume its previous performance when the patient is removed from the source of interference.

Through publications in the medical literature and through manufacturers' efforts, physicians who use and implant pacemakers have had the opportunity to be well informed over the years as to potential interference sources. Of greater concern are those physicians and paramedical personnel both within and outside of the hospital environment having occasional contact with pacemaker patients who may not be well informed of these hazards.

The manufacturers of pacemakers have and are making an increased effort to disseminate information to physicians, paramedical persons and patients pointing out the possible causes of pacemaker interference. Efforts are also being made to reduce the sensitivity of pacemakers to electrical interference. We bring this to your attention, as you may want to have your personnel well aware and ready to react in cases of pacemaker dysfunction in the presence of R-F diathermy.

We believe extreme care should be taken in the application of R-F diathermy on pacemaker patients. It is also important to note that the antennas of microwave diathermy machines radiate enough energy in several directions to cause modification of pacemaker function. Therefore, hospital employees and patients who have implanted pacemakers should avoid those areas where diathermy machines are in operation.

We would also recommend that the information in this letter be brought to the attention of your attending staff, nursing staff, and other hospital employees. At the hospital level, steps should be taken to prevent pacemaker patients from encountering interference sources as microwave ovens, diathermy, etc.

We believe you are sufficiently aware of the possible medical-legal implications, should such an untoward event occur, that further emphasis of our desire to protect the patient is unnecessary.

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Telephone: (301) 530-2800

TO: Hospital Administrators

FROM: AAMI Standards Subcommittee on Pacemakers

SUBJECT: Microwave Radiation and Pacemakers

SUMMARY: Microwave radiation, in addition to other sources of electrical field interference, can modify the function of some pacemakers under certain conditions. Under most conditions this is not considered to be a problem of major concern to an estimated 50,000 patients that are wearing pacemakers.

External electrical interference[1] has been studied and reported in some detail since pacemakers were first developed. Most of the literature concerns those products and frequency ranges that the person would most likely come in contact with in a normal daily existence. In rare cases, implanted pacemakers dysfunction has been observed near electro cautery and diathermy apparatus; microwave ovens, radar, and communications systems; electric shavers, spark coils, and gasoline engine ignition systems. With the recent and anticipated expansion of the use of microwave ovens in residences, hospitals, and commercial food servers, it is necessary to also consider this product's possible additional interference with pacemaker function.

The body, a conductive medium, provides good shielding from most interfering sources. However, external non-competitive pacemakers and units designed for implantation, when tested externally, are much more susceptible to electrical interference.

A number of surveys have been conducted by various groups on the leakage levels found in microwave ovens in commercial and home use.

Voluntary standards of manufacture have permitted emission levels up to 10 milliwatts per sq. cm. at a distance of 2 inches. The usual leakage is around the door seal. Some ovens, particularly those in heavy commercial use, have been found to have leakage emissions above this level. In rare instances emissions as high as 200 mw/sq. cm. at 2 inches have been recorded.

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1 Parker, Bryan, Seymour Furman and Doris J.W. Esher, Input Studies to Pacemakers in A Hospital Environment. Annals of the N.Y. Academy of Sciences, Vol. 167, Article 2, pp 823-834.

The Department of Health, Education, and Welfare, Environmental Health Agency has promulgated (in the Federal Register of October 6, 1970, Vol. 35, No. 194) a radiation standard for all microwave ovens manufactured after October 6, 1971, underwhich newly manufactured ovens must not emit radiation at a power density exceeding 1 milliwatt per sq. cm. at any point 2 inches or more from the oven surface. To allow for wear after sale to a customer, the proposed standard allows that the power density at any point may increase to 5 milliwatts per sq. cm. It is estimated that 75,000 ovens will be marketed and in use under the present 10 milliwatt standard, before the new standard becomes effective.

There are two major classifications of pacemakers, the fixed (asynchronous) rate type and the non-competitive type (i.e., demand, standby, ventricular, inhibited, ventricular triggered, atrial triggered). These pacemakers units may be implanted internally, within the body or may be attached externally outside of the body.

The fixed rate pacemaker has a low frequency oscillator designed to deliver pulses at the desired cardiac stimulation rate. Such units are unaffected by any electrical interference situation which the patient may encounter, with the exception of electric cautery used within a few inches of the unit and RF diathermy applied directly to the pacemaker site. In addition to the oscillator, the non-competitive pacemaker contains electronic circuitry (designed to sense electrical cardiac activity), to modify the output of the pacemaker, should a natural contraction occur within the prescribed timing interval. This type of pacemaker is susceptible to microwave radiation of sufficient intensity. Diathermy should not be used on pacemaker patients without full recognition of the interference potential.

Any interference signal entering the electronic circuitry of the non-competitive pacemaker, which mimics the electrical signal corresponding to a normal heartbeat may be interpreted by the pacemaker as a normal heartbeat and cause changes in the pacemaker's output.

The patient's response to these effects on his pacemaker will depend on the mode of operation of the pacemaker, his individual cardiac condition and whether the pacemaker is implanted or external. Depending upon the type of pacemaker, it may speed up - producing limited tachycardia, revert to a fixed rate, or inhibit its output. Patients with ventricular inhibited pacemakers may have a normal cardiac rate without pacing. These patients would likely feel nothing, as the heart has already inhibited the pacemaker. If the patient's non-paced rate is quite low, and the pacemaker is totally inhibited by the interference, the patient might experience dizziness and possible loss of consciousness (Stokes-Adams Syndrome). Such inhibition can be hazardous to the patient who is totally pacemaker dependent. It is important to recognize that the pacemaker is not damaged by electrical interference and will resume its previous performance when the patient is removed from the source of interference.

Through publications in the medical literature and through manufacturers' efforts, physicians who use and implant pacemakers have had the opportunity to be well informed over the years as to potential interference sources. Of greater concern are those physicians and paramedical personnel both within and outside of the hospital environment having occasional contact with pacemaker patients, who may not be well informed of these possible hazards.

The manufacturers of pacemakers have and are making an increased effort to disseminate information to physicians and patients pointing out the possible causes of pacemaker interference. Efforts are also being made to reduce the sensitivity of pacemakers to electrical interference. We bring this to your attention, as you may want to have your microwave ovens checked and maintained for proper leakage levels, and if possible kept away from pacemaker patient areas. Appropriate information is available from the manufacturers.

We would also recommend that the information in this letter be brought to the attention of your attending staff, nursing staff, and other hospital employees. At the hospital level, steps should be taken to prevent pacemaker patients from encountering interference sources such as microwave ovens, diathermy, etc.

We believe you are sufficiently aware of the possible medical legal implications should such an untoward event occur, that further emphasis of our desire to protect the patient is unnecessary.

DIVISION OF ELECTRONIC PRODUCTS

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(continued from inside of front cover)

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